Butler, Jennie C

From: gwilcox@ioa.com
Sent: Saturday, May 15, 1999 7:00 PM
To: FDADockets@test.oc.fda.gov
Subject: RE: Proposed Rule to Ban Substances in Animal Food [Docket No.

SUBJECT too long. Original SUBJECT is
RE: Proposed Rule to Ban Substances in Animal Food [Docket No. 96N-0135]

---------- Original Message Follows ----------

Dockets Management Branch (HFA-305)
Food and Drug Administration
12420 Parklawn Dr.
Rm. 1-23
Rockville, MD 20857

RE: Proposed Rule to Ban Substances in Animal Food [Docket No. 96N-0135]

Dear Madam or Sir:

I am writing on behalf of Farm Sanctuary, a national non-profit organization which works to stop irresponsible agricultural practices.

While we commend the Food and Drug Administration (FDA) for proposing to ban the use of certain rendered products in the feed of ruminants, we write today because we believe the agency must take additional measures to ameliorate the risk of bovine spongiform encephalopathy (BSE) or a similar disease from spreading in the U.S.

RECOMMENDATIONS:

To begin with, we would recommend that the use of rendered products in poultry feed be carefully examined, particularly because poultry litter is used in cattle feed. The ruminant to ruminant feed ban should also apply to ruminant protein recycled through poultry.

We also strongly oppose the "No Action" alternative described in the proposed rule, and dispute the contention that, "...BSE has not been detected in cattle in the U.S. despite an extensive surveillance effort that has been in place for several years." In 1985, there was an incident involving minks in Wisconsin and follow up research indicating the likelihood of an unrecognized BSE-like disease in U.S. cattle. Evidence suggests that cattle in the U.S. afflicted with a BSE-like disease become "downed" (i.e. they are unable to stand and walk without assistance) instead of "mad" like in Britain. Given this possibility, we recommend that the FDA prohibit the use of downed animals for food. (This is discussed in further detail below.)

THE "NO ACTION" ALTERNATIVE IS SUPPORTED BY INSUFFICIENT EVIDENCE:

We do not believe there has been "an extensive [BSE] surveillance effort" in the U.S. as FDA asserts. In fact, only an extremely small number of animals have been tested for BSE. The effectiveness of this surveillance effort is also questionable because it has focused on symptoms typical of Mad Cow Disease in Britain. It is possible that a U.S. variant of BSE may cause other symptoms. Specifically, U.S. cattle may not display jittery ("mad cow") behavior like British cattle, and they may not have the same sponge-like brain lesions. We believe the U.S. surveillance program needs to be expanded to, among other things, include detailed post-mortem studies of "suspect" cattle who are slaughtered for human consumption.

One of the FDA's alternative proposals prohibits only tissues shown to transmit spongiform encephalopathies (eg. brain, eyes, spinal cord) from being used in the feed of ruminants. We would caution against this

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because it is possible that other, as yet undiscovered, tissues harbor the infective agent. This possibility was recently bolstered by evidence of vertical transmission of BSE from cow to calf. It is also possible, if not likely, for tissues which are considered safe to be contaminated during slaughter and processing. A recent Texas A & M study found that captive bolt stunning, the most commonly used method in cattle slaughterplants, causes head trauma which spreads brain material throughout the animals' bodies.

THE U.S. MAY HAVE ITS OWN VARIANT OF BSE IN DOWNED COWS:

The FDA's surveillance effort has not adequately considered that downed cattle may harbor a variant of BSE. Farm Sanctuary investigators have travelled throughout the U.S. documenting the presence of nonambulatory livestock (often referred to as "downed animals") at stockyards and slaughterhouses. These are severely incapacitated animals who are unable to stand and walk on their own. They are routinely used for human food, a practice we believe poses human health risks, including the potential threat of a BSE-like disease. Our concern that downed cattle may harbor a variant of BSE is based largely on evidence that downed cattle have caused encephalopathy in minks.

The history of transmissible mink encephalopathy (TME) in the U.S., justifies the FDA prohibiting the use of mink by- products in ruminant feed. We commend the FDA for proposing this action, however, we believe it is also important for the FDA to heed evidence that these TME outbreaks may have been precipitated by infected cattle.

Since 1947, 11 U.S. mink farms are known to have been affected by TME. Nine of these were in Wisconsin, one was in Minnesota, and one was in Idaho. It is likely that these outbreaks were caused by contaminated feed, given that farms affected by the disease commonly shared the same feed source. Information was not available about feed ingredients for six of the eleven affected farms, but on the other five, a common ingredient was found: meat from downed cattle.

The last TME outbreak recorded in the U.S. occurred in Stetsonville, WI in 1985. This incident was subsequently studied by Dr. Richard Marsh of the Department of Animal Health and Biomedical Sciences at the University of Wisconsin, Madison. His research was published (Dev Biol Stand. Basel, Karger, 1993, vol 80, pp 111-118) and provides compelling evidence that downed cattle in the U.S. may harbor a variant of BSE.

Marsh inoculated two cattle with brain material from TME infected mink from the Stetsonville, WI farm. Within two years, both cattle became "downed". Then, Marsh fed brain tissue from these affected cattle to minks, and found that minks exhibited a TME-like disease within seven months. Referring to this, Marsh wrote, "These findings are compatible with the Stetsonville incident of TME being caused by feeding mink infected cattle tissue and they suggest the presence of an unrecognized BSE-like disease in the United States (emphasis added)". Unfortunately, Marsh was not funded to conduct further research in this area.

It should be noted that minks have historically served as "sentinel animals" for harmful substances in the environment. For example, they were the first species to show the deleterious effects of PCBs on reproduction. It is possible that these "sentinel animals" are telling us something about downed cows.

Marsh's research is bolstered by evidence that sheep infected with scrapie (the related brain disease in sheep) in the U.S. cause cattle to become "downed" instead of "mad". Many scientists believe BSE was spread in Britain when sheep infected with scrapie were fed to cows. In the U.S., scientists wondered whether scrapie from U.S. sheep would also cause Mad Cow Disease, so they inoculated cattle with scrapie from U.S. sheep. The inoculated cattle became "downed," not "mad". R.C. Cutlip et al reported, "Thus, undiagnosed scrapie infection could contribute to the 'downer-cow' syndrome [in the U.S.]..." (Journal of Infectious Diseases 1994; 169:814-20).

Tens of thousands of downed cattle are slaughtered for human food in the

U.S. every year. These animals are not examined for BSE, and the reason for their nonambulatory state is usually unknown. We are concerned that some of these animals may be infected with a BSE-like disease.

If downed cattle in the U.S. harbor a variant of BSE, and if the disease can cross the species barrier from cattle to humans as recent findings in Britain suggest, the human health implications could be disastrous. Accordingly, we believe it is necessary for FDA to prohibit the use of downed cattle for human food.

THE FDA SHOULD NOT ALLOW SHORT TERM ECONOMIC CONSIDERATIONS TO HINDER OR PREVENT NECESSARY ACTION TO PROTECT HUMAN HEALTH:

Downed animals represent an extremely small percentage of all livestock slaughtered, and banning their use would provide no undue economic hardship. Even if there is some economic hardship, this consideration must not outweigh the threat to human health.

Tragically, short term economic considerations have tended to hinder government and industry action necessary to protect consumers. A January 20, 1997 article from Feedstuffs stated:

A report of the European Parliament's inquiry into bovine spongiform encephalopathy (BSE) was released in Brussels, Belgium, last week, placing blame for the management of the cattle disease squarely on the British government; the European Union Agricultural Council, made up of member states' farm ministers, and the European Commission. The report from the inquiry charged that British and European officials gave "priority to the interests of market management, as opposed to the potential human health risks existing in the light of the numerous scientific uncertainties concerning the possible effects of BSE on humans. There is a considerable body of material confirming this attitude." Furthermore, the inquiry committee said, "The present committee considers that the commission has displayed negligence with respect to the adoption and monitoring of human and animal health protection measures."

We are distressed that economic priorities have tended to take precedence over the health of consumers. We are also concerned that, like in Britain, a powerful economic incentive exists to ignore evidence that BSE, or a variant of BSE, exists in the U.S.

CONCLUSION:

We urge the FDA to examine the scientific evidence regarding BSE carefully and to act in the interest of American consumers. We cannot afford to make the same mistakes that were made in Britain.

Sincerely,

Gregory Wilcox
Arthur D. Little, Inc.
31 Overlook Drive
Candler, NC 28715-9260
(828) 665-7531
(617) 498-5476 (voice mail)
(617) 498-7161 (fax)
Email address: wilcox.g@adlittle.com (work)
gwilcox@a-o.com (home)
RiskWorks home page: http://www.process-safety.com
Personal home page: http://www.erols.com/rwilcox/greg.html
ZPG/Boston home page: http://www.fas.harvard.edu/~jtownsen/zpg-boston/